K092711

510(K) SUMMARY

1. SUBMITTER:

Zerusa Limited
219-220 Business Innovation Centre, NUIG
Galway, Ireland
Telephone: 011-353-91-861611
Establishment Registration Number: 3005395947

Official contact: Mr. Liam Mulloy, CEO
Phone: 011-353-91-863060
Date Prepared: August 31, 2009

OCT - 1 2009

2. DEVICE:

Tradename:	Guardian™ II Hemostasis Valve
Classification Name:	Cardiopulmonary Bypass Adaptor, Stopcock, Manifold or Fitting
Classification:	Class II
Common Name:	Hemostatic Valve
Product Code:	74 DTL
Regulation Number:	870.4290

3. PREDICATE DEVICE:

This current 510(k) Premarket Notification is being submitted for the following changes:

- Reduce overall Hemostasis Valve product length
- Reduce length of the Guidewire Introducer provided for use with the HV
- Incorporate a dead stop on the lower body
- Add a Parylene N coating to the O-ring
- Change printed graphics color from Sericol white to Sericol black
- Remove 8% Blue Polycarbonate Master Batch 23034 Granulate tint from the Rotolock and Luer on the HV

The predicate device used to determine substantial equivalence for this device was the Zerusa Limited's currently marketed Guardian™ Hemostasis Valve (#K052381 and #K073620).

4. DEVICE DESCRIPTION:

The Zerusa Guardian™ II Hemostasis Valve is designed to be used as a conduit when interventional devices with diameters up to 8.0F (2.67mm or 0.105") are inserted into the human vascular system.

The device has two seals: the low-pressure seal (or wiper seal) and the high-pressure seal. Depressing the cap engages the Quikloc™ to open the low-pressure seal, depressing the cap again closes the seal. The high-pressure seal is operated by rotating the nut clockwise. Closure of the high-pressure seal, which is achieved when the nut can no longer rotate, secures the diagnostic/interventional device in position within the vasculature and also allows for pressure injections up to 150 psi (10 ATM).

Included with the Guardian™ II Hemostasis Valve is a Guidewire Introducer, which is used to facilitate entry of the guidewire into the Guardian™ II Hemostasis Valve. It consists of an austenitic stainless steel tube connected to a hub constructed of polycarbonate.

Also included with the Guardian™ II HV is a simple Guidewire Torquer which is used to manipulate the steering of a guidewire within the vascular regions.

5. INTENDED USE:

The Guardian™ II Hemostasis Valve is intended to maintain hemostasis during the introduction, withdrawal and use of diagnostic/interventional devices during vascular procedures.

6. INDICATIONS FOR USE:

The Guardian™ II HV is intended to maintain hemostasis during the use of diagnostic/interventional devices. The device is indicated for maintaining a seal around diagnostic/interventional devices with outside diameters up to 8.0F (2.67 mm or 0.105") during diagnostic/interventional procedures.

The guidewire introducer is included to facilitate the guidewire's passage through the Guardian™ II HV.

The Torque Device is intended to manipulate the steering of the guidewire within the vascular regions.

7. COMPARISON OF CHARACTERISTICS:

Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are identical or substantially equivalent to the currently marketed predicate devices.

8. PERFORMANCE DATA:

The Guardian™ II Hemostasis Valve was subjected to a full battery of performance testing. The results of the performance testing demonstrated the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Zerusa Limited
c/o Mr. Liam Mulloy
219-220 Business Innovation Centre, NUIG
Galway, Ireland

OCT - 1 2009

Re: K092711
Guardian™ II Hemostasis Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DTL
Dated: August 31, 2009
Received: September 3, 2009

Dear Mr. Mulloy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092711

Device Name: Guardian™ II Hemostasis Valve

Indications for Use: The Guardian™ II HV is intended to maintain hemostasis during the use of diagnostic/interventional devices. The device is indicated for maintaining a seal around diagnostic/interventional devices with outside diameters up to 8.0F (2.67 mm or 0.105") during diagnostic/interventional procedures.

The guidewire introducer is included to facilitate the guidewire's passage through the Guardian™ II HV.

The Torque Device is included to manipulate the steering of the guidewire within the vascular regions.

Prescription Use XXX (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092711

(Posted November 13, 2003)